Amendment and Response [Under 37 C.F.R. §1.116 - Expedited Examining Procedure]

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Serial No.: 10/728,439 Confirmation No.: 9418 Filed: 5 December 2003

05/19/2008 14:25 FAX 6123051228

For: POLYMER COMPOSITIONS WITH BIOACTIVE AGENT, MEDICAL ARTICLES, AND METHODS

## Remarks

The Office Action mailed March 31, 2008 has been received and reviewed. Claims 27, 42, and 53-55 having been amended, the pending claims are claims 1-10, 12-45, 48-50, 53-55, 58-60, and 75. Reconsideration and withdrawal of the rejections are respectfully requested.

## **Double Patenting Rejection**

Claims 7-10, 12, 19-45, 48-50, 58, and 60 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-15, 17-19, 22-25, and 71 of co-pending Application No. 10/728,577 (published as US 2004/0180093). Upon an indication of otherwise allowable subject matter and in the event this rejection is maintained, Applicants will provide an appropriate response.

## The 35 U.S.C. §112, Second Paragraph, Rejection

The Examiner rejected claims 42 and 54 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Specifically, the Examiner objected to the incorporation of "a tackifier" in claim 42 since claim 27 recites that the polymer composition is nonadherent. Claim 42 having been amended, this rejection is rendered moot.

The Examiner also objected to claim 54 because of the phrase "wherein the hydrophobic polymer is mineral oil." Claim 54 has been amended to clarify that the dispersion (which includes absorbent hydrophilic microparticles) includes mineral oil. This amendment is supported by Applicants' specification at page 10, lines 4-6 and renders the rejection moot.

Withdrawal of these rejections is respectfully requested.

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## The 35 U.S.C. §103 Rejection

The Examiner rejected claims 7-9 and 12 under 35 U.S.C. §103 as being unpatentable over Highgate (U.S. Patent No. 4,768,503) in view of Asmus (U.S. Patent No. 5,270,358). The Examiner rejected claim 10 under 35 U.S.C. §103 as being unpatentable over Highgate (U.S. Patent No. 4,768,503) in view of Asmus (U.S. Patent No. 5,270,358) and further in view of Ahmed et al. (U.S. Patent No. 6,458,877). The Examiner rejected claims 19-39, 42-45, 48-50, 53, 55, and 58-60 under 35 U.S.C. §103 as being unpatentable over Highgate (U.S. Patent No. 4,768,503) in view of Asmus (U.S. Patent No. 5,270,358) and further in view of Takemori et al. (U.S. Patent No. 5,075,373). The Examiner rejected claims 40 and 41 under 35 U.S.C. §103 as being unpatentable over Highgate (U.S. Patent No. 4,768,503) in view of Asmus (U.S. Patent No. 5,270,358) and Takemori et al. (U.S. Patent No. 5,075,373) and further in view of Ahmed et al. (U.S. Patent No. 6,458,877). The Examiner rejected claims 1-4, 6, and 75 under 35 U.S.C. §103 as being unpatentable over Highgate (U.S. Patent No. 4,768,503) in view of Asmus (U.S. Patent No. 5,270,358) and further in view of Laurin et al. (U.S. Patent No. 4,603,152). The Examiner rejected claim 5 under 35 U.S.C. §103 as being unpatentable over Highgate (U.S. Patent No. 4,768,503) in view of Asmus (U.S. Patent No. 5,270,358) and Laurin et al. (U.S. Patent No. 4,603,152) and further in view of Ahmed et al. (U.S. Patent No. 6,458,877). The Examiner rejected claims 13-18 under 35 U.S.C. §103 as being unpatentable over Highgate (U.S. Patent No. 4,768,503) in view of Asmus (U.S. Patent No. 5,270,358) and Laurin et al. (U.S. Patent No. 4,603,152) and further in view of Yan et al. (U.S. Patent Publication No. 2003/0185889). These rejections are respectfully traversed.

Highgate discloses a polymeric composition which has <u>sealant</u> and preferably also adhesive properties. The composition is used as a <u>sealing ring</u> in conjunction with a post-surgical drainage appliance (e.g., ostomy bag). The formation of a <u>seal</u> with the skin is a requirement of the polymeric composition of Highgate. "A <u>reliable seal</u> between the skin of the patient and an ostomy appliance, such as a drainage bag or pouch, <u>is essential</u> in order, inter alia, to prevent leakage and/or irritation of the skin" (column 1, lines 22-26, emphasis added). "Similarly, drainage bags or pouches are worn by patients to drain faecal fistulae, urinary fistule

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the skin of the patient and the drainage bag or pouch is required" (column 1, lines 27-31, emphasis added). "According to one aspect of the present invention the polymeric composition according to the invention may be suitable for use as a protective dressing simply having sealant properties without any adhesive properties and it has been found that it is sometimes desirable to separate these functions. In the case where, for example, the dressing is in the form of a sealing ring used in conjunction with a drainage bag or pouch then a separate adhesive material or a mechanical securing aid would be employed" (column 3, lines 1-10, emphasis added). Therefore, whether it has adhesive properties or not, the polymeric composition of Highgate needs to "seal" (or, in Applicants' terms "adhere") to the skin of a patient.

As explained at page 5, lines 10-17 of Applicants' specification, the polymer composition itself is nonadherent (to steel per the test outlined, and preferably to wound tissue), although the nonadherent composition could be used in combination with a pressure sensitive adhesive, for example, in an article (e.g., a wound dressing).

There is no teaching or suggestion in Highgate (or any motivation provided by any of the other documents cited by the Examiner) to make a nonadherent composition, i.e., one that does <u>not scal</u> to the skin of a patient. Reconsideration and withdrawal of these rejection are respectfully requested.

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# Summary

It is respectfully submitted that the pending claims 1-10, 12-45, 48-50, 53-55, 58-60, and 75 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted By Mueting, Raasch & Gebhardt, P.A. P.O. Box 581415 Minneapolis, MN 55458-1415

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May 19, 2008

Date

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#### CERTIFICATE UNDER 37 CFR \$1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 17 day of May, 2008, at 211000 (Central Time).

By: SanEW&F Name: Sava E Wigard